

REMARKS

Claims 1, 3, 5-10, 12-31, and 35-82 were pending in the present application. Claims 3, 5, 6, 12-26, 35-77, and 79-82 had been withdrawn from consideration after restriction under 35 U.S.C. § 121. Claims 1, 7-10, 27-31, and 78 are under consideration. In the present Office Action, claims 1, 7-10, 27-31, and 78 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by International Application WO 99/20614 (the '*614 application*'). Claims 1, 7-10, 27-31, and 78 also have been rejected under 35 U.S.C. § 102(a) as allegedly anticipated by International Application WO 00/66572 (the '*572 application*'). Claims 1, 7-10, 27-31, and 78 also have been rejected under 35 U.S.C. § 103 as allegedly obvious over the '*614 application* in view of U.S. Patent No. 5,646,172 to Claussner et al. ("Claussner"). Finally, claims 1, 7-10, and 27-31 also have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

By this Amendment, Applicants canceled claims 1, 7, and 27-31 without prejudice to presenting the subject matter of these claims in a continuation application. Applicants also amended claims 8-10 and 78 and added new claims 83-86. The amendments and the new claims are supported in the application as originally filed. No new matter is introduced by the amendments and the new claims, and, accordingly, Applicants request entry of these amendments. Furthermore, reconsideration and allowance of all now-pending claims in view of the amendments and remarks below are respectfully requested.

I. REJECTIONS UNDER 35 U.S.C. § 102

The Examiner has rejected claims 7, 27, 28, 30, and 31 as allegedly anticipated by the '*614 application*'. The Examiner also has rejected claims 1, 7, 27, 28, 30, 31, and 78 as allegedly anticipated by the '*572 application*'. Claims 27, 28, 30, and 31 have been canceled from the present application and thus these rejections are moot with respect to claims 27, 28, 30, and 31.

Claim 78 recites a salt of metformin. Neither the '*614 application*' nor the '*572 application*' disclose salts of metformin. If the Examiner believes otherwise, Applicants respectfully request the Examiner to point to the corresponding location in the cited references. However, to anticipate a claim, a single prior art reference must teach every element of the claims. See M.P.E.P. §2131. Therefore, Applicants

respectfully maintain that neither the '614 *application* nor the '572 *application* anticipate claim 78.

Four specific compounds previously recited in canceled claim 7 are now recited in new claims 83-86. Thus, the rejections over the '614 *application* and the '572 *application* will be addressed below.

Neither the '614 application nor the '572 application specifically disclose the salts of new claims 83-86. In making the anticipation rejection over the '614 *application*, the Examiner combined Examples 29 and 30 (p. 58) and the description of suitable salts (p. 15, Ins. 15-22). Examples 29 and 30 describe a free acid and a sodium salt of a given compound. The list of salts describes the salts suitable for the genus of compounds. Likewise, in making the anticipation rejection over the '572 *application*, the Examiner combined the Examples (e.g., at p. 67) with the description of salts for the genus (pp. 17-18).

However, such combination of separate excerpts from a reference cannot be used to establish a case of anticipation. See, e.g., MPEP §2131, citing *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as in the claim") and *In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990) (explaining that the elements must be arranged as in the claim). To arrive at the claimed salts, the Examiner would have to select the compound of Example 29 from the numerous examples and combine it with one of the salts from the list that describe the salts suitable for the genus. However, to anticipate a claim to a compound, the reference must "clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures . . . [emphasis added]" See *In re Arkley*, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972).

Therefore, Applicants respectfully assert that neither the '614 *application* nor the '572 *application* can form a basis for a case of anticipation against any claim presently in the application.

II. THE REJECTION UNDER 35 U.S.C. § 103

In making an obviousness rejection over the '614 *application* in view of *Claussner*, the Examiner stated, "it would have been obvious . . . to prepare salts of the carboxylic acid compounds [of the '614 *application*] using any of the organic bases, including those taught by the secondary reference [Claussner], as they are

taught to be equivalent [language in brackets added]." See Office Action mailed June 17, 2004, which is incorporated by reference in the present Office Action.

Applicants respectfully maintain that the Examiner's rationale is not applicable to any claim presently in the application.

First, to set forth a *prima facie* case of obviousness over a combination of references, the Examiner must show that there is some suggestion or motivation in the prior art to combine the references in the direction of the claimed invention. See M.P.E.P. §2143.01. Nothing in the cited references suggest specifically modifying the free acid of Example 29 or the sodium salt of Example 30 in the direction of the present claims 78 and 83-86, let alone the dependent claims 8-10.

Furthermore, the prior art must suggest "the desirability of the claimed invention." See MPEP §2143.01. In other words, to establish a *prima facie* case of obviousness, the Examiner must show a motivation or suggestion to combine "the relevant teachings of the references." See *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Applicants respectfully point out that claims presently in the application are directed to specific salts of specific compounds. Thus, to arrive at the claimed invention, the Examiner would have to select the compound of Example 29 from the numerous examples and combine it with the specific salts from *Claussner*. What is the motivation or suggestion to make such selections of specific salts and compounds? Thus, even assuming, *arguendo*, that the teachings of the cited reference were combined, the references, alone or in combination, do not suggest or motivate a selection of the specific salts and specific compounds claimed.

On the basis of the foregoing, Applicants respectfully assert that claims 8-10, 78, and 83-86 are not *prima facie* obvious over the cited references, alone or in combination.

III. THE REJECTION UNDER 35 U.S.C. § 112

The Examiner has rejected claims 1, 7-10, and 27-31 under 35 U.S.C. §112, second paragraph, for certain recitations in claims 1 and 7. Applicants note that the claim cancellations and amendments fully addressed this rejection. Acknowledgement to this effect is respectfully requested.

It is believed that all rejections in the outstanding Office Action had been fully met. Allowance of all pending claims is respectfully requested. The Commissioner is hereby authorized to charge any fee which may be required, or credit any overpayment, to Deposit Account No. 50-3221.

Respectfully submitted,



Edward D. Pergament
Attorney for Applicants
Reg. No. 43,346

Dated: 8/25/2008
Dr. Reddy's Laboratories, Inc.
200 Somerset Corporate Blvd.
Seventh Floor
Bridgewater, NJ 08807-2862
Telephone No.: (908) 203-6500
Facsimile No.: (908) 203-6515